IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION – CINCINNATI

DIANNA SCHOTT, et al., **Plaintiffs,** **v.** **I-FLOW CORPORATION, et al.,** **Defendants.**	**Case No. 1:08-cv-00323-SAS-TSB** **Judge S. Arthur Spiegel** **Magistrate Judge Timothy S. Black**
MICHELLE KASSELMAN-SCHOETTMER, et al., **Plaintiffs,** **v.** **I-FLOW CORPORATION, et al.,** **Defendants.**	**Case No.: 1:08-cv-00700-SAS-TSH** **Judge S. Arthur Spiegel** **Magistrate Judge Timothy S. Hogan**
RIAN MUZIK, **Plaintiff,** **v.** **I-FLOW CORPORATION, et al.,** **Defendants.**	**Case No. 1:08-CV-00818-SAS-TSH** **Judge S. Arthur Spiegel** **Magistrate Judge Timothy S. Hogan**
MARTIN MITCHENER, **Plaintiff,** **v.** **I-FLOW CORPORATION, et al.,** **Defendants.**	**Case No. 1:09-cv-00155-SAS-TSB** **Judge S. Arthur Spiegel** **Magistrate Judge Timothy S. Black**
AMY WEST AND VINCE WEST, **Plaintiffs,** **v.** **I-FLOW CORPORATION,** **Defendant.**	**Case No. 1:09-CV-00098-SAS-TSH** **Judge S. Arthur Spiegel** **Magistrate Judge Timothy S. Hogan**

DEFENDANT I-FLOW CORPORATION'S
MOTION FOR SUMMARY JUDGMENT

Defendant I-Flow Corporation ("I-Flow"), by and through counsel, and pursuant to Rule 56 of the Federal Rules of Civil Procedure, hereby moves this Court for an order granting summary judgment in favor of I-Flow and against Plaintiffs in the above-captioned actions. This Motion is supported by the attached Memorandum and Declaration in Support of Matthew V. Brammer, Esq.

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF DEFENDANT I-FLOW CORPORATION'S MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Defendant I-Flow Corporation ("I-Flow"), by counsel, hereby moves for summary judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure, with regard to the above-captioned Plaintiffs' respective claims for punitive damages against I-Flow on grounds that Plaintiffs have failed to adduce sufficient evidence to support such a claim.

In addition, I-Flow requests that the Court defer any summary judgment ruling as to Plaintiffs' claims for strict products liability, negligence, breach of warranty and loss of consortium until such time as the Court has heard and decided I-Flow's *Daubert* motions to exclude Plaintiffs' proffered causation expert testimony, which is being filed concurrently with the instant Motion. As grounds, I-Flow states that it will be entitled to summary judgment, as a matter of law, as to all claims against it in the event that said motion(s) are granted.

In further support of this Motion, I-Flow states as follows:

II. UNDISPUTED MATERIAL FACTS

Pending against I-Flow are Plaintiffs' claims for relief for strict products liability, negligence, breach of warranty, loss of consortium (with the exception of the *Mitchener* case), and punitive damages. *See* Mitchener Complaint; Schoettmer First Amended Complaint; Schott Amended Complaint; West Complaint; and Muzik Complaint.

More specifically, Plaintiff Martin Mitchener, claims that he underwent a shoulder surgical procedure on June 29, 2006, and that in conjunction with said procedure an ON-Q® PainBuster® Post-Op Pain Relief System ("ON-Q® PainBuster®"), which was manufactured by I-Flow, was implanted into his shoulder joint by his orthopedic surgeon, Dr. Jonathan Paley. Mitchener Complaint, ¶¶ 1, 9. Plaintiff Rian Muzik claims that he underwent a shoulder surgical

procedure on January 12, 2007, and that in conjunction with said procedure an ON-Q® PainBuster® was implanted into his shoulder joint by his orthopedic surgeon, Dr. Keith A. LaDu. Muzik Second Amended Complaint, ¶ 8. Plaintiffs Michelle Kasselman-Schoettmer and Mark Schoettmer, Dianna Schott and Raymond Schott, and Amy West and Vince West, claim, respectively, that Ms. Schoettmer underwent a shoulder surgical procedure on June 21, 2007, Ms. Schott underwent a shoulder surgical procedure on May 10, 2007, and Ms. West underwent a shoulder surgical procedure on June 27, 2007, and that in conjunction with each of these procedures an ON-Q® PainBuster® was implanted into each personal injury plaintiff's shoulder joint by her orthopedic surgeon, Dr. Paul Favorito.

Plaintiffs claim that the ON-Q® PainBuster® injected pain relief medication directly into each personal injury plaintiff's shoulder joint on a continuous basis, for up to two days or more following their respective surgeries. It is claimed that the personal injury plaintiffs sustained injuries to their shoulders as a result of the postoperative use of the ON-Q® PainBuster® in this manner. *See* Mitchener Complaint, ¶¶ 9-11; Muzik Second Amended Complaint, ¶¶ 8-10. Schoettmer First Amended Complaint, ¶¶ 8-10; Schott Amended Complaint, ¶¶ 8-10; West Complaint, ¶¶ 6-8.

III. APPLICABLE LEGAL STANDARDS

A. Summary Judgment

Summary judgment is proper when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Where the movant shows that no genuine issue of fact exists for trial, the non-moving party cannot rest on the

pleadings but must respond with evidence setting out "specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2).

Importantly, a moving defendant is entitled to summary judgment where the plaintiff fails to establish the existence of an essential element of her claim. *See Celotex v. Catrett*, 477 U.S. 317, 322-324 (1986), *cited in Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715, 721-722 (N.D. Ohio 2007). Moreover, in moving for summary judgment where a plaintiff fails to satisfy this burden, the moving party is not required to submit evidence or affidavits to support its motion. *See id.* at 322-324.

Indeed, as the United States Supreme Court has stated:

> In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be no genuine issue as to any material fact, since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is entitled to a judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential element of [the nonmoving party's] case with respect to which she has the burden of proof.

Id. at 322-323 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)) (internal quotation marks omitted). The Supreme Court has further stated:

> [W]e find no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent's claim. On the contrary, Rule 56(c), which refers to the affidavits, if any, suggests the absence of such a requirement. And if there were any doubt about the meaning of Rule 56(c) in this regard, such doubt is clearly removed by Rules 56(a) and (b), which provide that claimants and defendants, respectively, may move for summary judgment with or without supporting affidavits. The import of these subsections is that, regardless of whether the moving party accompanies its summary judgment motion with affidavits, the motion may, and should, be granted so long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c), is satisfied. One of the principal purposes of the summary judgment rule is to

> isolate and dispose of factually unsupported claims or defenses, and we think it should be interpreted in a way that allows it to accomplish this purpose.

Anderson v. Liberty Lobby, Inc., 477 U.S. at 323-324 (internal quotation marks omitted).

B. Punitive Damages

Plaintiffs' entitlement to recover punitive damages is governed by Ohio substantive law. In Ohio, to recover punitive damages in a product liability action, a plaintiff must establish "by clear and convincing evidence, that the harm for which the claimant is entitled to recover compensatory damages … was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product." Ohio Rev. Code Ann. § 2307.80 (A); *see also* Ohio Rev. Code Ann. § 2307.72. As a prerequisite to recovering punitive damages, a plaintiff must show that he or she was damaged as a result of the defendant's alleged misconduct – in other words, a plaintiff must establish a *causal* connection between the defendant's alleged misconduct and the plaintiff's alleged injuries. *See* Ohio Rev. Code Ann. § 2307.80 (A).

Importantly, a plaintiff may not recover punitive damages from a medical device manufacturer if the "device that allegedly caused" the plaintiff's harm "was manufactured and labeled in relevant and material respects in accordance with the terms of approval or license issued by the federal food and drug administration under the 'Federal Food, Drug, and Cosmetic Act.' Ohio Rev. Code Ann. § 2307.80 (C)(1)(a).

IV. ARGUMENT

A. Summary judgment is appropriate as to Plaintiffs' claims for punitive damages against I-Flow.

1. Plaintiffs have failed to adduce sufficient evidence to support their punitive damages claims

Pursuant to Ohio Rev. Code Ann. § 2307.80 (A), Plaintiffs in this litigation are required to prove that their alleged injuries and damages were the result of "misconduct" by I-Flow "that manifested a flagrant disregard of the safety of persons who might be harmed by the" ON-Q® PainBuster®. Plaintiffs, however, have failed to adduce sufficient evidence to satisfy their burden in the above-captioned cases.

In support of their punitive damages claim, Plaintiffs allege that I-Flow: (i) "failed to warn against" continuous infusion of local anesthetics into the shoulder joint; (ii) "actively market[ed the ON-Q® PainBuster®] to be used in shoulder surgeries where pain relief was required in the intra-articular space of the shoulder joint;" (iii) "instructed physicians to place the tip of the catheter in the intra-articular space of the shoulder joint;" and (iv) did so "without conducting any safety tests and/or clinical trials" and "with actual knowledge of scientific studies, peer-reviewed journal articles, and reported cases demonstrating a link between chondrolysis and prolonged exposure of articular cartilage to Marcaine and epinephrine" or "bupivacaine and epinephrine." Mitchener Complaint, ¶¶ 39-40; Muzik Second Amended Complaint, ¶¶ 38-39. Schoettmer First Amended Complaint, ¶¶ 42-43; Schott Amended Complaint, ¶¶ 41-42; West Complaint, ¶¶ 27-28.

First, there is absolutely no credible evidence that I-Flow or any of its representatives "instructed" or otherwise recommended that Plaintiffs' surgeons, Dr. Favorito (Schoettmer, Schott and West), Dr. Paley (Mitchener) and/or Dr. LaDu (Muzik), place the ON-Q®

PainBuster® catheter in the intra-articular space of the shoulder joint. As such, Plaintiffs' generic and conclusory allegations to the contrary, as stated in (iii) above, is without support in these cases, which in turn is fatal to their punitive damages claims.

Specifically, Dr. Favorito began using pain pumps which were manufactured by Breg in 1999. *See* **Ex. 40**, Dr. Favorito's May 18, 2009 Deposition, at 9. At that time, Dr. Favorito learned, by observing attending physicians, to insert the pain pump catheter where it was felt that there would be the most pain generation, including in the shoulder joint. *See id.* at 10-11. Importantly, Dr. Favorito did not begin using I-Flow pain pumps until 2005 or 2006 and testified that no one from I-Flow ever directed him to insert the pain pump catheter into the intra-articular space. *See id.* at 22, 181. Dr. Favorito does not recall seeing any I-Flow catheter placement guide for intra-articular use and has no knowledge of any I-Flow representative telling surgeons that the catheter could be used for intra-articular placement. *Id.* at 100-101. Dr. Favorito testified that it is the surgeon's choice as to where to place the pain pump catheter and what medications and dosages to administer. *See id.* at 111-112.

Similarly, Dr. Paley and Dr. LaDu do not recall what documents or information, if any, they may have received from I-Flow or the contents thereof. *See* **Ex. 411**, Dr. Paley's October 22, 2009 Deposition, at 14-16; **Ex. 43**, Dr. LaDu's September 22, 2009 Deposition, at 23-24, 27-30. Neither Dr. Paley nor Dr. LaDu recalls receiving any information from I-Flow recommending where the pain pump catheter should be placed.[2] *See* **Ex. 41** at 21; **Ex. 43** at 49,

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1 Throughout, references to exhibits are references to the attachments to the *Declaration in Support of Defendant I-Flow Corporation's Motion to Exclude Plaintiffs' General Causation Experts, Motions to Exclude Testimony of Dr. Jason Louis Dragoo, Dr. Sander Greenland, Dr. Martin Wells and Peggy Pence, and Motion for Summary Judgment*, submitted concurrently herewith.

2 While Dr. LaDu testified that pain pump sales representatives "alluded" that the pain pump catheter could be placed intra-articularly, he testified that he communicated with sales representatives from various pain pump

97-98. Like Dr. Favorito, Dr. Paley and Dr. LaDu placed pain pump catheters where, in their opinion, the majority of the pathology was and the pain pump would be the most beneficial. *See* **Ex. 41** at 19-21; **Ex. 43** at 36-37.

Second, Plaintiffs' contentions stated in (i) and (ii) above are wholly insufficient to support a punitive damages claim. This is because mere failure to warn, by statute, is insufficient to establish a flagrant disregard for the safety of others. *See* Ohio Rev. Code Ann. § 2307.80 (A) ("The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product."). Further, that the ON-Q® PainBuster® may have been marketed and sold to surgeons and/or facilities which perform shoulder surgical procedures is equally insufficient as the general indications for use cleared by the FDA include orthopedic applications and certainly do not exclude the specific indication for intra-articular use. *See* Ohio Rev. Code Ann. § 2307.80 (C)(1)(a). Indeed, as recognized by Plaintiffs' regulatory expert, Peggy Pence, Ph.D., RAC, pain pumps, such as the ON-Q® PainBuster®, "can be sold to orthopedic surgeons for use [] as prescribed in the [] FDA cleared labeling" and that orthopedic physicians may use a product in an "on-label or off-label" manner. **Ex. 39**, Pence's December 1, 2009 Deposition, at 117, 173; *see also* **Ex. 38**, Pence's October 6, 2009 Deposition, at 87-89.

Third, relative to Plaintiffs' allegations as stated in (iv) above, there is no evidence that I-Flow engaged in any of the conduct complained of "with actual knowledge" of published literature "demonstrating a link between chondrolysis and prolonged exposure of articular cartilage to Marcaine and epinephrine" or "bupivacaine and epinephrine." Notably, I-Flow has

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manufacturers and he does not recall whether an I-Flow representative actually communicated this to him. *See* **Ex. 43** at 144-146.

long-warned against use of epinephrine in its pain pumps. Moreover, even if Plaintiffs allegations were true, which I-Flow contends they are not, epinephrine was **not** used in the pain pumps prescribed to any of the personal injury plaintiffs in the above-captioned cases. *See* **Ex. 42**, Medical Records (filed under seal).

Finally, as addressed in I-Flow's motion to exclude Plaintiffs' causation experts filed concurrently herewith and briefly below in Section IV(B), postarthroscopic glenohumeral chondrolysis ("PAGCL"), the condition about which Plaintiffs claim I-Flow should have warned, is a very recent and rare phenomenon and its causation is not known or well understood by the medical and scientific community even to this day. *See* **Ex. 6,** Lubowitz and Poehling, *Glenohumeral Thermal Capsulorrhaphy Is Not Recommended – Shoulder Chondrolysis Requires Additional Research*, 23 ARTHROSCOPY 687 (July 2007) ("Future research is required to determine the cause, and proper prevention, of shoulder chondrolysis."); **Ex. 5**, Baillie *et al., Severe Shoulder Chondrolysis After Shoulder Arthroscopy: A Case Series*, J. SHOULDER ELBOW SURG. 1, 2 (2009) ("The etiology [of chondrolysis] remains elusive but may be multifactorial, given the variety of reported associations and presumed causes. However, the actual cause of even the reported cases has not been confirmed, and the associations are speculative at this juncture."). Indeed, as recently as four months ago, leading medical researchers candidly acknowledged that "the exact cause of chondrolysis after labral repair has not been determined" and that "to date, no single etiology has been identified as the cause of chondrolysis associated with anterior shoulder instability repair.…" **Ex. 1**, Kang, *et al., Complications Associated with Anterior Shoulder Instability Repair*, 25 Arthroscopy 909, 914 (August 2009). In light of the state of medical and scientific knowledge regarding chondrolysis, not only at the time of the personal injury Plaintiffs' respective surgeries between June 2006 and June 2007, but also at

present, Plaintiffs cannot establish that I-Flow engaged in conduct which amounted to a "flagrant disregard for the safety" of others as required by statute.

Because Plaintiffs have failed to adduce sufficient evidence to establish a claim for punitive damages against I-Flow under Ohio statutory law, I-Flow is entitled to summary judgment and dismissal of Plaintiffs' respective punitive damages claims.

2. I-Flow is entitled to summary judgment to the extent Plaintiffs' punitive damages claims are based on claimed duties which do not exist.

In addition, I-Flow is entitled to summary judgment to the extent that Plaintiffs' punitive damages claims are based on claimed duties which do not exist. Specifically, to the extent that Plaintiffs claim that the use of the ON-Q® PainBuster® in the joint space is "off label," which I-Flow denies, there is no duty to test or perform clinical trials for off-label uses of a 5l0(k) device. *See Valentine v. Baxter Healthcare Corp.*, 68 Cal. App. 4th 1467, 1485-1486 (1999). Nor is there a duty to inform the medical community that a specific indication for use with respect to a 510(k) device was not cleared by the FDA. Indeed, a physician is expected to read and understand FDA-approved labeling and to know the labeled indication for a prescription device. *See* 21 C.F.R. 801.109; 21 U.S.C. § 39; FDCA § 906; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ("*Buckman*"). I-Flow's Motion for summary judgment should, therefore, be granted on this ground as well.

3. I-Flow is entitled to summary judgment to the extent Plaintiffs' punitive damages claims are based on alleged violations of FDA regulations.

Finally, I-Flow is entitled to summary judgment to the extent that Plaintiffs attempt to support their punitive damages claims with alleged violations of FDA regulations as such claims are pre-empted pursuant to the holding of the United States Supreme Court in *Buckman*, 531

U.S. 341. In *Buckman*: (i) the plaintiffs' claims were based on allegations that the manufacturer of orthopedic bone screws made misrepresentations to the FDA during the same 510(k) clearance process that applied to the pain pump which is the subject of Plaintiff's claims; (ii) the FDA approved the marketing of the bone screws for certain uses, but refused to clear them for use in spinal surgery; (iii) the plaintiffs alleged that they were injured during off-label use of the screws in their spines; and (iv) the plaintiffs filed state law claims against the manufacturers for fraud-on-the-FDA. *See Buckman*, 531 U.S. 341. In holding that such claims are pre-empted, the Supreme Court stated:

> Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law."

Id. at 348.

The Court provided several reasons for its holding in *Buckman*, and each of the reasons is applicable to Plaintiffs' claim for punitive damages in this litigation. First, the FDA is empowered to enforce its regulations and penalize offenders. *See id.* Second, "off-label usage of medical devices (use of a device for some purpose other than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Id*. at 350-351 (citations omitted) (discussing the benefits of off-label use and the dangers of subjecting 510(k) applicants to the "unpredictable civil liability" based on alleged violations of FDA regulations). Finally, the Court recognized the danger that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the [FDA], will later be judged insufficient in state court." *Id.* at 351.

> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.

Id. at 353.

The existence of the federal enactments is a critical element to the arguments made in support of Plaintiffs' claim for punitive damages in this case. Thus, to the extent Plaintiffs' claims for punitive damages are based on alleged violations of FDA regulations, summary judgment is appropriate in accordance with *Buckman* as such claims are impliedly pre-empted.

B. Because I-Flow will be entitled to summary judgment where the Court excludes Plaintiffs' proffered causation expert testimony, I-Flow requests that the Court defer any summary judgment ruling as to Plaintiffs' claims for strict products liability, negligence, breach of warranty and loss of consortium.

Pursuant to the scheduling orders in the above-captioned cases, I-Flow is filing motions to exclude Plaintiffs' expert causation testimony, pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), concurrently with this motion for summary judgment. In the event that I-Flow's motions are granted, I-Flow will be entitled to summary judgment, as a matter of law, as to all claims against it. *Botnick*, 484 F. Supp. 2d 715, 724 (N.D. Ohio 2007) (granting defendant's motion for summary judgment in product liability action where plaintiffs failed to produce admissible expert testimony on medical causation).

Specifically, under Ohio law, to prevail on their claims for strict product liability, negligence, breach of warranty and loss of consortium against I-Flow, Plaintiffs must establish causation between their alleged injuries and damages, on the one hand, and I-Flow's alleged acts or omissions, and/or the alleged product defects or deficiencies, on the other hand. *See Parsley v. Hamilton Beach/Proctor Silex, Inc.*, 494 F. Supp. 2d 858, 862 (S.D. Ohio. 2007) (noting that

strict product liability and breach of warranty claims both require preponderance of the evidence proof that the alleged defect "was the direct and proximate cause of" the alleged injuries or loss); *Reece v. AstraZeneca Pharmaceuticals, LP*, 500 F. Supp. 2d 736, 751 (S.D. Ohio 2007) (noting that claim for negligent failure to warn requires proof that alleged injury was proximate cause of alleged breach of duty). "To prove proximate causation for medical conditions or illnesses caused by a defective product, a plaintiff must show by a reasonable degree of medical certainty that the disease or injury was caused by the defective product." *See Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d at 724 (citations omitted). Moreover, in this prescription medical device case, Plaintiffs must establish both: (1) general causation, i.e., that I-Flow's product can cause the type of harm complained of; and (2) specific causation, i.e., that I-Flow's product did cause each Plaintiff's or Plaintiffs' alleged injuries. *See In re Meridia*, 328 F. Supp. 2d 791, 798 (N.D. Ohio 2004). Because the element of causation in this litigation involves a complex medical question, Plaintiffs may only establish general causation and specific causation by way of admissible expert testimony. *See Botnick*, 484 F. Supp. 2d at 724 ("Under Ohio law, a plaintiff must present expert medical testimony to establish causation when she asserts a specific physical injury, the cause for which is not within common knowledge."), and cases cited therein; *Darnell v. Eastman*, 261 N.E.2d 114, 116 (Ohio 1970).

Plaintiffs cannot provide a legitimate scientific basis for causation in the above-captioned cases, and thus, I-Flow is entitled to summary judgment as to all claims against it, for all of the reasons stated in I-Flow's motions to exclude, which are filed concurrently herewith and which are incorporated herein by reference. Nonetheless, in order to provide context to this motion, I-Flow briefly notes the following:

Each personal injury Plaintiff in the above-captioned cases underwent shoulder surgery for reasons unrelated to Plaintiffs' liability claims against I-Flow. It is claimed that the personal injury Plaintiffs developed shoulder chondrolysis at some point after their respective surgeries and purported ON-Q® PainBuster® use. Plaintiffs allege that the use of an ON-Q® PainBuster® for continuous infusion of local anesthetics into the intra-articular space of the personal injury Plaintiffs' shoulder joints caused their chondrolysis.

However, no one – not the personal injury Plaintiffs' treating physicians, nor Plaintiffs' cadre of experts, nor even the defense experts – knows, on the basis of reliable scientific evidence, whether continuous infusion causes chondrolysis. As recently as four months ago, leading medical researchers candidly acknowledged that "the exact cause of chondrolysis after labral repair has not been determined" and that "to date, no single etiology has been identified as the cause of chondrolysis associated with anterior shoulder instability repair…." **Ex. 1**, Kang, *et al.*, *Complications Associated with Anterior Shoulder Instability Repair*, 25 Arthroscopy 909, 914 (August 2009). Throughout the robust debate in the scientific and medical community about the purported relationship between continuous infusion and chondrolysis, this constant emerges: No published researcher has claimed that continuous infusion *causes* chondrolysis:

> "Although intra-articular pain pumps, radiofrequency devices, and hardware problems such as prominent anchors have been described, the causes of PAGCL are still not completely understood. . . . The role of intra-articular catheters and pumps in pain management after shoulder surgery has not been substantiated. . . ." **Ex. 2**, McNickle *et al.*, *Postsurgical Glenohumeral Arthritis in Young Adults*, Am. J. Sports Med. (2009)

> ". . . [T]he etiology of chondrolysis remains unclear." **Ex. 3**, Coobs & LaPrade, *Severe Chondrolysis of the Glenohumeral Joint After Shoulder Thermal Capsulorrhaphy*, 38 Am. J. Orthop. E34, E36 (2009).

> "Although the etiology of these cases is not known for certain, there has been speculation that radiofrequency devices, young patient age, instability surgery, intra-articular pain pumps, and type of anesthetic may be precipitating factors."

> **Ex. 4**, Saltzman *et al.*, *Postsurgical Chondrolysis of the Shoulder*, 32 Orthopedics 215, 215 (2009).
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> ". . . [T]he actual cause of even the reported cases has not been confirmed, and the associations are speculative at this juncture." **Ex. 5**, Bailie *et al.*, *Severe Chondrolysis After Shoulder Arthroscopy: A Case Series*, J. Shoulder Elbow Surg. 1, 2 (2009).
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> "The etiology of glenohumeral chondrolysis may be multifactorial. Future research is required to determine the cause, and proper prevention, of shoulder chondrolysis." **Ex. 6**, Lubowitz & Poehling, *Glenohumeral Thermal Capsulorrhaphy Is Not Recommended—Shoulder Chondrolysis Requires Additional Research*, 23 Arthroscopy 687 (July 2007).
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> "We believe that further investigation of the possible association of pain pump use with chondrolysis is warranted." "The cause of this process [of chondrolysis] is unknown. . . . Postarthroscopic glenohumeral chondrolysis is a devastating complication that has yet to be etiologically defined." **Ex. 7**, Hansen *et al.*, *Postarthroscopic Glenohumoral Chondrolysis*, 35 Am. J. Sports Med. 1628, 1632-1633 (July 2007).
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> .
> "Although the cause is uncertain, this complication appears to occur most commonly in young patients who have undergone shoulder reconstructive procedures to manage shoulder instability." **Ex. 8**, Sanders *et al.*, *Chondrolysis of the Glenohumeral Joint After Arthroscopy: Findings on Radiography and Low-Field-Strength MRI*, 188 Am. J. Rad. 1094, 1094 (April 2007).
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> "Post-arthroscopic shoulder chondrolysis is a devastating complication. No etiology has been firmly identified and treatment options are limited." **Ex. 9**, Hansen *et al.*, *Post-Arthroscopic Shoulder Chondrolysis With Associated Intraarticular Pain Pump Catheter Use*, Am. Acad. Orthop. Surg. Ann. Mtg. (March 23, 2006).
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> "The disease pathophysiology is currently not understood. . . . We do not know the natural history of this process." **Ex. 10**, Petty *et al.*, *Glenohumoral Chondrolysis After Shoulder Arthroscopy: Case Reports and Review of Literature*, 32 Am. J. Sports Med. 509, 514 (2004).

The existing data bearing on the etiology of chondrolysis do not permit anyone to conclude scientifically that intra-articular infusion of local anesthetics by a pain pump causes chondrolysis. This consensus that a causal link between continuous infusion and chondrolysis

has not been reliably established unmasks Plaintiffs' expert causation opinions as no more than "leaps of faith" unsupported by good science.

As explained above, an essential element of Plaintiffs' respective claims is proof to a reasonable degree of medical certainty by way of admissible expert testimony that use of an ON-Q® PainBuster® for continuous infusion of local anesthetics into the intra-articular space of the shoulder joint causes chondrolysis. Plaintiffs rely upon their purported causation experts in these cases (1) Dr. Jason Dragoo, (2) Dr. Martin Wells, and (iii) Dr. Sander Greenland, for this assertion. However, as discussed very briefly above, and for the reasons set forth in I-Flow's Fed. R. Evid. 702 motions to exclude filed contemporaneously herewith, Plaintiffs' expert causation opinions are unsupported and cannot pass muster under Rule 702 and the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Indeed, the only court in the country to address the issue of whether a plaintiff can establish general causation – i.e. whether pain pumps can cause chondrolysis – concluded that this opinion is not admissible under Rule 702, and therefore summary judgment was appropriate for the defendant pain pump manufacturer. *See* **Ex. 25**, *Kilpatrick v. Breg, Inc.*, No. 08-10052-CV, 2009 WL 2058384 (S.D. Fla. June 25, 2009). Plaintiffs, therefore, cannot prove general causation in these cases.

In accordance with the foregoing, I-Flow is entitled to summary judgment as to all claims against it. *See, e.g., Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244 (6th Cir. 2001) (affirming order granting defendants' motion to exclude plaintiffs' causation experts and granting defendants' motion for summary judgment due to plaintiffs' failure to establish causation by way of admissible expert opinions or testimony). I-Flow requests that the Court defer any summary judgment ruling as to Plaintiffs' claims for relief for strict products liability,

negligence, breach of warranty and loss of consortium until such time as the Court has heard and ruled on I-Flow's motions to exclude Plaintiffs' causation expert(s).

V. CONCLUSION

For the foregoing reasons, Defendant I-Flow Corporation, by counsel, respectfully requests that this Court grant I-Flow's Motion for Summary Judgment and enter an Order dismissing Plaintiffs' respective claims for punitive damages. In addition, Defendant I-Flow Corporation requests that the Court defer any summary judgment ruling as to Plaintiffs' claims for strict products liability, negligence, breach of warranty, and loss of consortium until such time as the Court has heard and ruled on I-Flow's motion to exclude Plaintiffs' causation expert(s).

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CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2010, I electronically filed the foregoing *Defendant I-Flow Corporation's Motion for Summary Judgment and Memorandum in Support Defendant I-Flow Corporation's Motion for Summary Judgment* with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses:

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and I hereby certify that I mailed or served the document or paper to the following non-CM/ECF participants in the manner (mail, hand-delivery, etc.) indicated by the non participant's name:

NONE

/s/ Lisa Marlo Miller
Lisa Marlo Miller

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